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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,459	10/06/2003	Chris Rundfeldt	HUBR-1230	4494

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
12/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/680,459	RUNDFELDT ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-17, 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-17, 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicants present arguments over the 35 USC 103 rejection. In particular, Applicants argue that French teaches that patients respond differently to treatment and should be considered with Berendt (which is provided by the Applicant) which investigates the comparison between human epilepsy and epilepsy in dogs and an editorial by Podele showing the difficulty in the application of definitions of human epilepsy to dogs.

In response to the above arguments, it is noted that Berendt teaches that there are similarities with regards to seizure types and epilepsy classification between humans and dogs. Berendt acknowledges that a number of clinical signs described in humans can never be confirmed in animals, which is an drawback of utilizing animal models in general. Despite this drawback, Berendt draws conclusions from the study as well as prior human studies in which there is a correlation between humans and dogs in the types of seizures, including idiopathic seizures (see Types of Epilepsies on page 19). Though Podele raises questions as to the classification of seizures between adults and humans, he does point out that there are important similarities between the two, including the subject of the present invention which is idiopathic epilepsy (see last paragraph on page 4). Further Podele simply raises questions but does not provide studies with conclusory evidence to back up his assertions. Therefore, the Examiner takes the stand that both dogs and humans have idiopathic epilepsy and treatment regimens for both may possibly be similar. Further, the French reference was used in

for the teaching of treating types of idiopathic epilepsy in rats and mice which are often used as animal models for drug development and it is also noted that studies were pointed out that included drug treatment in dogs as well.

Applicants argue that Ross discusses the AGS model and that AGS in rodents is an animal model for epilepsy. Applicants argue that the word epilepsy is used generally and not for idiopathic epilepsy. Applicants also argue that the primary reference does teach a new anti-epileptic drug; however, absence seizures are known to occur in several forms of epilepsy.

In response to this argument, and as the definition of epilepsy provided by Applicant shows, epilepsy is a general term that includes the different types including idiopathic. Further, the teachings of Bialer teach rodent models for AGS or absence epilepsy of which absence epilepsy is specifically taught as a form of idiopathic epilepsy by French. In addition, while it may be true that absence seizures occur in several forms of epilepsy, it is noted that one would not exclude idiopathic epilepsy as a viable treatment option with the drug because it is know that absence seizures occur in idiopathic epilepsy.

Accordingly, the rejections are maintained and given below for Applicant's convenience.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12-15 and 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Bialer et al. (J Epilepsy Research (Jan 2001) 43, pgs. 11-58) in view of Ross et al. (Neurosci Biobehav Rev, 24 (2000) 639-653) and French (Am J Managed Care, Vol. 7, No. 7, 2001).

Bialer et al. teach that AWD 131-138 treats audiogenic clonic seizures in genetic models of epilepsy (meeting the limitation of claim 12; pg. 12, Section 2.1.1.1). Because it is taught that AWD 131-138 has anticonvulsant activities in animal models of epilepsy, it is obviously taught that AWD 131-138 would effectively treat epilepsy regardless of when it was diagnosed (meeting the limitation of claim 19). Though Bialer et al. does not teach the treatment of dogs with AWD 131-138 in the AGS model, the treatment of dogs is taught in other models. Therefore, there would be a reasonable expectation of success that AWD 131-138 would be an effective treatment for idiopathic epilepsies.

Bialer et al. does not specifically state that the forms of epilepsies are idiopathic.

Ross et al. teach that AGS is a form of epilepsy associated with generalized seizure displayed by clonic or tonic-clonic seizure activity (see first paragraph of Introduction).

French teaches that clonic or tonic-clonic seizure activity is a form of idiopathic epilepsy (see Role of New AEDs on page S209).

Because Ross et al. and French teach that AGS is a form of idiopathic epilepsy, it would be obvious to a person of ordinary skill in the art at the time of the invention that Bialer et al. is teaching the treatment of different forms of idiopathic epilepsy with AWD 131-138. Though Bialer et al. does not teach the treatment of dogs with AWD 131-138 in the AGS epilepsy model, the treatment of dogs is taught in other models. Therefore, there would be a reasonable expectation of success that AWD 131-138 would be an effective treatment for idiopathic epilepsies. One would be motivated to treat idiopathic epilepsy with AWD 131-138 with a reasonable expectation of success because it is taught that AWD 131-138 is effective in treating AGS, which is a form of idiopathic epilepsy.

It is noted that the claim limitation of "...said idiopathic epilepsy being characterized by excessive transient paroxysmal neuronal discharge in the cerebral cortex of said dog, when no underlying cause can be found via clinical and pathological examination..." refers to the mechanism of action of the idiopathic epilepsy. If it is determined that the treatment will treat idiopathic epilepsy, then it will obviously treat idiopathic epilepsy, regardless of how it is characterized.

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bialer et al. (J Epilepsy Research (2001) 43, pgs. 11-58) in view of Ross et al. (Neurosci Biobehav Rev, 24 (2000) 639-653) and French (Am J Managed Care, Vol. 7, No. 7, 2001) as applied to claims 12-15 and 19 above, in view of Thomas (Veterinary Clinics of North America Small Animal Practice (2000), 30, pgs. 183-206).

Bialer et al. teach that AWD 131-138 treats idiopathic epilepsy in dog seizure models as described in the above rejection.

Bialer et al. does not teach the co-administration of another active ingredient.

Thomas et al. teach that Phenobarbital is the initial choice of treatment for idiopathic epilepsy in dogs (meeting the limitations of claims 16-17; pg. 191, Choice of Treatment).

It would be obvious to one having ordinary skill in the art at the time of the invention that AWD 131-138 would be successful in treating idiopathic epilepsy in dogs by the teachings of Bialer et al., which teach that AWD 131-138 is effective in treating animal-models of idiopathic epilepsy. Furthermore, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, it would be obvious to co-administer another active ingredient such as Phenobarbital because it is useful in the treatment of idiopathic epilepsies as taught by Thomas et al. One would be motivated to administer the combined treatment with a

reasonable expectation of success because both AWD 131-138 and Phenobarbital are taught to effectively treat idiopathic epilepsy.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/
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